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| ELLIS, SUEZU Y | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/563,253

Applicant(s)

KONG ET AL.

Examiner

Suezu Ellis

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF-08)
- Paper No(s)/Mail Date 7/11/08
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

RESPONSE TO AMENDMENT

Response to Arguments

Applicant's arguments with respect to claims 1-9 and 11-12 have been considered but are moot in view of the new ground(s) of rejection.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on July 11, 2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-8 are 35 U.S.C. 103(a) as being unpatentable over Kasuga et al. (US 4,960,733) in view of Provenzano et al. (US 6,007,926) in view of Nawa et al. (US 2002/0198602).

With respect to claim 1, Kasuga et al. discloses in Examples 1, 2 and 6, comprising a zirconia-alumina nano-composite powder and an apatite-related compound, wherein zirconia primary particles and the alumina particles are sintered to form the composite in a secondary particle state (col. 2, lines 46-48; col. 4, lines 49-63). Kasuga et al. discloses the size of the zirconia-alumina nano-composite powder being have a larger (finer) size than 200 meshes, therefore is considered to have a particle size less than 74 μm (col. 4, lines 5-43). However, Kasuga et al. fails to expressly disclose the sizes being in the claimed ranges. Provenzano et al. discloses a zirconia-alumina ceramic formed from zirconia and alumina particles having particle sizes of 10 nm (col. 2, lines 35-39; col. 4, lines 32-35). It would have been obvious to one of ordinary skill in the art to modify the particle size of the alumina and zirconia particles to be about 10nm in order to provide a ceramic with a stabilized phase tetragonal phase of zirconia (col. 3, lines 40-43). It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Both Kasuga et al. and Provenzano et al. fail to disclose the nano-scale composite in a second particle state has a size of 100-200 nm. Nawa et al. discloses using zirconia-alumina composite ceramics for use in implants having second particle state with a size of 0.1-0.65 μm , thereby encompassing the claimed range [0026]. It

would have been obvious to one of ordinary skill in the art to modify the size of the second particle state in order to provide a composite ceramic with a increased wear resistance and high strength and high toughness [0026], [0057]. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claims 3-5, the modified Kasuga et al. discloses in Example 2, Kasuga et al. discloses the ceramic composite comprises 20 vol % of apatite-related compound and 80 vol % zirconia-alumina nano-composite powder (col. 8, lines 11-12).

With respect to claim 6, the modified Kasuga et al. discloses the zirconia in the zirconia-alumina nano-composite powder is 60% weight (col. 3, lines 54-57).

With respect to claim 7, the modified Kasuga et al. discloses in Examples 2 and 6, the zirconia-alumina nano-composite powder further comprises yttrium oxide.

With respect to claim 8, the modified Kasuga et al. discloses in Table 1, No. 2 (corresponds to Example 1) the apatite-related compound is converted into tricalcium phosphate. However, the modified Kasuga et al. fails to expressly disclose the amount of apatite-related compound that is converted. It would have been obvious to one of ordinary skill in the art to modify the amount of compound to be converted in order to create the desired amount of tricalcium phosphate.

Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hermansson et al. (US 5,306,673) in view of Provenzano et al. in view of Nawa et al.

With respect to claim 1, Hermansson et al. discloses a sintered bioactive ceramic composite for implant comprising a zirconia-alumina composite powder and an apatite-related compound (col. 1, lines 51-65; col. 3, lines 21-23). Hermansson et al. fails to expressly disclose the particle sizes of the zirconium and aluminum oxides.

Provenzano et al. discloses a zirconia-alumina ceramic formed from zirconia and alumina particles having particle sizes of 10 nm (col. 2, lines 35-39; col. 4, lines 32-35). It would have been obvious to one of ordinary skill in the art to modify the particle size of the alumina and zirconia particles to be about 10nm in order to provide a ceramic with a stabilized phase tetragonal phase of zirconia (col. 3, lines 40-43), as desired. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Both Hermansson et al. and Provenzano et al. fail to disclose the nano-scale composite in a second particle state has a size of 100-200 nm. Nawa et al. discloses using zirconia-alumina composite ceramics for use in implants having second particle state with a size of 0.1-0.65 μm , thereby encompassing the claimed range [0026]. It would have been obvious to one of ordinary skill in the art to modify the size of the second particle state in order to provide a composite ceramic with a increased wear resistance and high strength and high toughness [0026], [0057]. Further, it has been

held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claim 2, the modified Hermansson et al. discloses the apatite-related compound being hydroxyapatite (col. 1, lines 59-60).

With respect to claims 3-5, the modified Hermansson et al. discloses the apatite-related compound is 5-35% by volume, therefore the zirconia-alumina nano-composite powder is 65-95% by volume (col. 1, lines 57-58). It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claim 7, the modified Hermansson et al. fails to expressly disclose the inclusion of an additional claimed metal oxide. Nawa et al. teaches including ceria (cerium oxide) in the zirconia-alumina nano-composite powder [0017]. It would have been obvious to one of ordinary skill in the art to include ceria in order to stabilize the tetragonal zirconia.

With respect to claim 8, the modified Hermansson et al. discloses the apatite-related compound is 5-35% by volume, and the apatite-related compound being tri-calcium phosphate (col. 1, lines 57-61).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hermansson et al. in view of Provenzano et al. in view of Nawa et al. and further in view of Kasuga et al.

With respect to claim 6, the modified Hermansson et al. addresses all the limitation of claim 1, however fails to expressly disclose the content of zirconia in the zirconia-alumina nano-composite powder being 50-99.9% by weight. Kasuga et al. teaches it is well known to use a zirconia-alumina ceramic having a weight ratio of 60:40 of zirconia to alumina for implants (col. 3, lines 54-57). It would have been obvious to one of ordinary skill in the art to modify the ratio content of zirconia to be greater than 50% by weight in order to attain a zirconia-alumina ceramic with higher strength and high toughness (col. 3, lines 45-47).

Claims 9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hermansson et al. in view of Zhen et al. (US 5,338,334).

With respect to claims 9 and 12, Hermansson et al. discloses a method of preparing a sintered bioactive ceramic composite for implant, comprising mixing zirconia-alumina composite powder with an apatite-related compound (hydroxyapatite) and sintering the mixture (col. 1, lines 51- col. 2, line 27). Hermansson et al. fails to expressly disclose the process of making the zirconia-alumina composite powder.

Zhen et al. discloses a method of preparing a zirconia-alumina nano-composite powder comprising the steps of mixing a solution of polyhydric alcohol and carboxylic acid and a mixed solution of zirconium salt and aluminum salt, heating the mixture to 80-150°C to form a polyester network in which zirconium ions and aluminum ions are trapped, and calcining the resultant at 400-1400°C (col. 4, lines 50-66; col. 5, line 51 – col. 6, line 19; col. 7, line 58 – col. 8, line 19). Although the temperature ranges of

Zhen et al. is not exactly the same as those claimed, the temperature ranges of Zhen et al. overlaps with those claimed, therefore one of ordinary skill in the art can attain a temperature within the claimed ranges. It would have been obvious to one of ordinary skill in the art to modify the temperature/temperature ranges of Zhen et al. since the temperature/temperature ranges is dependent on the nature of the ceramic powder and ceramic precursor utilize and on the particle size desired (col. 8, lines 5-11). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It has also been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)

It would have been obvious to one of ordinary skill in the art to utilize the zirconia-alumina composite powder of Zhen et al. in order to provide a zirconia-alumina composite powder with the desired particle size and free of significant impurities, as desired (col. 6, lines 14-19).

With respect to claim 11, the modified Hermansson et al. discloses the apatite-related compound is 5-35% by volume, therefore the zirconia-alumina nano-composite powder is 65-95% by volume (col. 1, lines 57-58).

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suez Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615